MAINE DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION
Office of Professional and Occupational Regulation
BOARD OF PHARMACY
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Janet T. Mills
Governor

BOARD STATEMENT #01-2022
MAINE BOARD OF PHARMACY

STATEMENT OF THE MAINE BOARD OF PHARMACY ON BEYOND-USE DATING OF INTRAVENOUS IODINATED CONTRAST MEDIA DRUGS DURING ACUTE SHORTAGE

It has come to the attention of the Maine Board of Pharmacy that there is currently an acute shortage in Maine and the United States of intravenous iodinated contrast media drugs (e.g., iohexol, ioversol, iodixanol) which are commonly used to add contrast to body parts and fluids to improve images obtained during a CT scan. This shortage is largely the result of the shutdown of a major production facility in Shanghai, China during a COVID-19 lockdown. The current shortage is expected to continue for at least 6-8 weeks.

Organizations that use intravenous iodinated contrast media drugs are undertaking efforts to conserve as much of these drugs as possible by adopting practices to minimize any wasting of the drugs. Such practices have included repackaging of bulk packages of these drugs into smaller containers in a sterile compounding environment. Such repackaging is considered medium-risk compounding under the United States Pharmacopeia (USP) Chapter <797> and requires the assignment of a beyond-use date ("BUD") for the repackaged product.

The USP has issued and updated the document, "Operational Consideration for Sterile Compounding During Covid-19 Pandemic", which provides guidance on the assignment of BUDs for low- and medium-risk compounded sterile preparations to address the management of drug supplies impacted by the COVID-19 pandemic. There is some concern by pharmacists in the sterile compounding community that adherence to this USP guidance in assigning BUDs to repackaged intravenous iodinated contrast media drugs, may in some instances technically conflict with the labeling of these products as approved by the U.S. Food and Drug Administration ("FDA").

Pursuant to Board Rules Chapter 29, (02-392 C.M.R. ch. 29), "unprofessional conduct" includes violations of certain rules of the FDA and certain reference standards of the USP.

IN ORDER TO PROTECT THE PUBLIC HEALTH AND WELFARE, THE BOARD ISSUES THE FOLLOWING CLARIFICATION:

For the period ending 90 days after the issuance of this Statement, the Board will not consider it "unprofessional conduct" for purposes of Board Rules Chapter 29, when a licensed pharmacist assigns a BUD to a repackaged intravenous iodinated contrast media drug, provided that the BUD complies with the guidance contained in the USP's "Operational Considerations for Sterile Compounding During Covid-19 Pandemic."

Issued: May 19, 2022

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